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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,019	09/21/2001	Chikara Aizawa	SHIM1120	9316

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,019	AIZAWA ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-15* is/are pending in the application.

4a) Of the above claim(s) *8-12,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-7, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Applicant's February 06, 2004 response is acknowledged. The traversal is on the ground(s) that the amended claims do not read on the prior art. This is not found persuasive because the lack of unity was made on the basis of the original claims, not the instantly amended claims. The original claims lacks unity of inventions because the special technical feature that was present in the claims at the time the lack of unity was made does not contribute over the prior art. WO 95/32737 teaches an attenuated clostridial toxin. Thus, because the special technical features of the previously presented claims are known over the prior art, it does not contribute over the prior art. Therefore, it thereby breaks the unity of the invention.

The requirement is still deemed proper and is therefore made FINAL.

Rejoinder of Claims

2. Upon review of the claims on the merits, the Examiner has rejoined claim 2 with the elected invention.

Status of Claims

3. Claims 1-3 and 6-15 are pending in the instant application. Claims 8-12 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Applicant's February 06, 2004 response. Accordingly, claims 1-3, 6-7 and 13 are currently under examination.

Claim Objections

4. Claim 1 is objected to because of the following informalities: The claim contains a limitation, staphylococcus alpha toxin and beta toxin, heat labile toxin of pathogenic E. coli, that is recited twice within the claim. This objection also affects claims 2-3, 6-7 and 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 6-7 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rappaport or Arciniega et al., respectively.

The claims are directed to an adjuvant that comprises an attenuated toxin having residual toxic activity of less than 1/2000, preferably 1/10000, of that of the natural toxin, wherein said toxin is selected from the group consisting of cholera, pertussis, heat-labile toxin of pathogenic E. coli, staphylococcus alpha toxin and beta toxin, and thermostable hemolytic toxin of Vibrio parahaemolyticus. The claims also recite a method which the attenuated toxin is prepared. Such limitation does not carry a patentable weigh because the claims are directed to a composition, not a method of making.

Rappaport et al. teaches an adjuvant that comprises attenuated cholera toxin, known in the art as cholera toxoid, that was chemically treated—as evidenced by Rappaport et al. earlier teaching, Infect. Immun. Vol 9, pp. 304-317.

Arciniega et al. teaches an adjuvant comprising pertussis toxoid, which as chemically treated (Inactivation of pertussis toxin with glutaraldehyde section of page 1133).

Neither Rappaport nor Arciniega et al. teach the level of toxicity of the toxoid when compared to the natural toxin. However, in the absence of evidence to the contrary, the toxoid taught by Rappaport or Arciniega et al. is the same as that instantly claimed because the toxoid of either Rappaport or Arciniega et al. share the same structural features defined by the claims. Therefore, Rappaport and Arciniega et al. anticipates the claimed invention.

If the toxoid taught by Rappaport and Arciniega et al. do not have the same level of toxin activity that is currently recited in the claims, at the time of the claimed invention it would have been obvious to one of ordinary skill in the art and one would have been motivated to optimize the toxoid by reducing the level of toxin activity as a matter of routine experimentation with reasonable expectation of success.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto or Kaper et al., in the alternative

The claims are directed to an adjuvant that comprises attenuated mutant toxin having a residual toxic activity of less than 1/2000, wherein said toxin is selected from the group consisting of cholera, pertussis, heat-labile toxin of pathogenic E. coli, staphylococcus alpha toxin and beta toxin, and thermostable hemolytic toxin of Vibrio parahaemolyticus. The claims also recite a method which the attenuated toxin is prepared. Such limitation does not carry a patentable weigh because the claims are directed to a composition, not a method of making and the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process

claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process, MPEP §2113, product-by-process.

Yamamoto et al. teaches an adjuvant that comprises an attenuated mutant toxin, which Yamamoto et al. regards as nontoxic mutant of cholera toxin. The adjuvant of Yamamoto et al. anticipates that of the instant invention. Furthermore, the level of toxic activity of the Yamamoto et al. adjuvant also anticipates that of the instant invention because Yamamoto et al. teaches an adjuvant that is nontoxic. Therefore, Yamamoto et al. anticipates the instantly claimed invention.

Kaper et al. teaches an adjuvant that comprises an attenuated mutant toxin, which Kaper et al. regards as recombinant non-toxinogenic cholerae. The adjuvant of Kaper et al. anticipates that of the instant invention. Furthermore, the level of toxic activity of the Kaper et al. adjuvant also anticipates that of the instant invention because Kaper et al. teaches an adjuvant that is nontoxinogenic. Therefore, Kaper et al. anticipates the instantly claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

Shanon Foley
Patent Examiner, AU 1648